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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary

Application No.

10/632,117

Applicant(s)

SMITH, HILDA ELIZABETH

Examiner

JaNa Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6, 7, 9 and 21-29 is/are pending in the application.
4a) Of the above claim(s) 1, 6, 7, 9, 28 and 29 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 21-27 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 8/7/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. The amendment filed September 24, 2008 has been entered. Claims 21, 26 and 29 have been amended. Claims 2-5, 8 and 10-20 are cancelled. Claims 1, 6-7, 9 and 28-29 are withdrawn from consideration. Claims 21-27 are under consideration in this office action.

Election/Restrictions

2. Previously submitted claims 28-29 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Original claim 11 was drawn to an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin comprising a nucleotide sequence capable of hybridizing to a nucleotide sequence selected from the group of nucleotide sequences consisting of SEQ ID NO: 37 or fragments thereof. It is noted that the claims were not drawn to a sequence comprising SEQ ID NO:37 as recited by claim 28; rather the claims were drawn to a nucleotide sequence capable of hybridizing to a nucleotide sequence. Therefore claims 28-29 are directed to an independent invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawal of Rejections

3. The enablement rejection of claims 21-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of applicants amendments and arguments.

Response to Arguments

4. Applicant's arguments filed September 24, 2008 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The written description rejection of claims 21-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record.

The claims are drawn to an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2, wherein the nucleic acid molecule remains hybridized after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium

dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C and wherein the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*.

Applicants' argue that paragraphs [0105]-[0106] describe the production and/or isolation of a 5kb fragment and pFBPS7-46, both of *Streptococcus suis* origin and that the specification demonstrates that the disclosed pFBPS7-46 and 5kb fragment include a nucleotide that hybridizes with nucleotides 89-263 of SEQ ID NO:37. However the issue is that the specification does not indicate that any nucleic acids that hybridize to SEQ ID NO:37 under the recited conditions and the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*. Thus applicants were not in possession of the isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*.

Applicants argue that the specification more than adequately discloses that the complement of the disclosed nucleotide sequence for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*. Contrary to applicants assertions, possession of SEQ ID NO: 37 does not equate to possession of an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *Streptococcus*

suis origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*. There is no disclosure of a nucleic acid molecule that hybridizes to SEQ ID NO:37 and the complement of the hybridizing nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*. Applicants arguments are not found persuasive.

Applicants assert that SEQ ID NO:37 is the complement of the claimed nucleotide sequence. However, because hybridization under highly stringent conditions requires a high degree of structural complementarity, nucleic acids that hybridize to SEQ ID NO:37 much share many nucleotides in common with SEQ ID NO:37. The disclosure of SEQ ID NO:37 combined with the knowledge in the art regarding hybridization would put one in possession of the genus of nucleic acids that would hybridize under the recited conditions to SEQ ID NO:37. Furthermore, the isolated or recombinant nucleic acid molecule comprises not only a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37, but possibly many other nucleotides which have not been described and which may or may not allow the complement of the nucleotide sequence to encode for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*. Thus, without a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing which of those nucleic

acids that hybridize to SEQ ID NO:37 wherein the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis* under the recited conditions. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. Despite Applicants efforts, the specification fails to provide guidance on the structure of the claimed nucleic acid molecule. Thus, those of ordinary skill in art would not consider applicant to have been in possession of the claimed genus of nucleic acid molecules based on the disclosure. Accordingly, applicants arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The new matter rejection of claims 21-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained fore reasons already of record.

Neither the specification nor originally presented claims provides support for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous

sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2, wherein the nucleic acid molecule remains hybridized after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C and wherein the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*.

Applicants' point to support in the specification for an isolated or recombinant nucleic acid at paragraph [0082]. However there is no disclosure of an isolated or recombinant nucleic acid molecule comprising a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37. There is no disclosure of a nucleic acid molecule wherein the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*. There appears to be no teaching of an isolated or recombinant nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a portion fibronectin-/fibrinogen-binding protein of *Streptococcus suis*. Furthermore, there is no teaching of the contiguous sequence hybridizing to the full length of nucleotides 89-263. Thus, it

appears that the entire specification appears to fail to recite support for the newly recited isolated or recombinant nucleotide sequence.

Despite applicants assertions, there appears that there is no support in the specification or the claims. Therefore, applicants must specifically point to page and line number support for the identity an isolated or recombinant nucleic acid molecule comprising wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 and wherein the complement of the nucleotide sequence encodes for a portion fibronectin-/fibrinogen-binding protein of *Streptococcus suis* as recited by the amended claims. Therefore, the claim incorporates new matter and the rejection is maintained.

Conclusion

7. No claims allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645